

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: de la Barrera Art Unit: 3739
App. No: 10/617,077 Examiner: Johnson III
Filed: 10 July 2003
Title: SURGICAL TOOL ASSEMBLY WITH A BATTERY
POWERED HANDPIECE FOR DRIVING AN ACCESSORY
AND A REMOVABLE TRACKING UNIT THAT PROVIDES
INFORMATION REGARDING THE POSITION OF THE
HANDPIECE, THE TRACKING UNIT BEING POWERED
BY THE HANDPIECE BATTERY

DECLARATION OF DON MALACKOWSKI
UNDER 37 SEC. 1.132

I Don Malackowski, residing at 16055 Prairie Ronde Road, Schoolcraft, Michigan, 49087 hereby state that:

1. I have a degree in electrical engineering technology from Purdue University.

1. I have been employed by the Stryker Corporation of Kalamazoo, Michigan since December of 1996. Since the start of my employment with Stryker, I have been involved in the design of powered surgical instruments. Since at least March of 1999 I have also been involved in the design of surgical navigation systems. As a result of my work, I am familiar with the design and design requirements of both battery operated powered surgical tools and surgical navigation systems.

2. I am part of the inventive entity that conceived of and constructively reduced to practice the navigation system trackers that are the subject of U.S. Pat. App. No. 09/764,609, now U.S. Pat. Pub. No. 2001/0034530.

3. The navigation components of both the tracker and smart tool of the '530 Publication are designed to achieve the specified run time with a battery that is capable of supplying at least 2.5 watt hours of power with a peak current delivery capability of 0.5 amps.

4. The tracker of the '530 Publication is designed for attachment to a powered surgical saw. This type of saw typically requires a battery capable of supplying 10 watt hours of energy and a peak current delivery capability of 40 amps.

5. Accordingly, a tracker with a battery capable of powering a surgical tool would require a battery capable of storing a larger charge, providing more power than required by the tracker navigation components. In a situation where this power was not required, the battery would be of a size and weight larger than what would be required just to supply the power for the tracker. This would be contrary to a goal of the design of surgical instruments; the instrument should be as light as possible to facilitate ease of use and reduce the physical fatigue of the user. As an alternative to providing an oversized battery, a smaller battery could be provided. This would increase the inventory burden on both the vendor of the tool and navigation system and on the facility at which the system is used. Therefore, the universal tracker that was constructed and that is the subject of this application does not have features that allow the battery integral with the tracker to serve as power supply for the instrument to which the tracker is attached.

6. As part of the reduction to practice of the system of the '530 Publication a combined pointer-and-tracker was constructed. There was no effort made to construct an assembly with a shared battery for powering both the handpiece power-consuming unit and the tracker navigation components.

7. The use of the term "common lithium battery" in the '530 Publication was meant to indicate that the battery is a well-known lithium battery, the CR2 lithium cell, available at the time the application upon which the '530 Publication is based was filed. This particular battery is used to power amateur cameras.

8. The charge stored in the above-identified battery could not deliver the required current to power a surgical saw. Thus, this battery cannot supply the power required to energize the power consuming components of the instruments for which the tracker of the '530 Publication is designed.


9. Given the above facts, I believe that an engineer skilled in the design of surgical navigation equipment would recognize the statement that the battery-at-issue is a "common lithium battery", as meaning the battery is well known lithium battery. The '530 Publication does not disclose how to make a powered instrument-and-tracker surgical tool assembly wherein the power for both the instrument and the tracker are supplied by a shared battery.

10. At the time tracker and smart instruments of the '530 Publication were being designed my employer was not

providing any battery powered instruments that were being powered with a lithium-cell batteries. NiCad cell batteries were used to power the instruments being provided by my employer. I am not aware of any entity in 2001 that was commercially producing battery powered surgical instruments that were powered by lithium cell batteries.

I, Don Malackowski, hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

September 27, 2007


Don Malackowski